UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

IN RE ATHENEX, INC. SECURITIES LITIGATION	21-CV-337-LJV-HKS DECISION & ORDER

On March 3, 2021, Naveen Gupta commenced this putative class action under sections 10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act"), 15 U.S.C. §§ 78j(b) and 78t(a). Docket Item 1. On April 28, 2021, the case was referred to United States Magistrate Judge H. Kenneth Schroeder, Jr., for all proceedings under 28 U.S.C. § 636(b)(1)(A) and (B). Docket Item 14. Several months later, this case was consolidated with *Koza v. Athenex, Inc.*, Case No. 21-cv-413 (W.D.N.Y. Mar. 22, 2021), and another member of the class of shareholders, John McKenzie, was appointed as lead plaintiff. Docket Item 46.

On January 25, 2022, the defendants moved to dismiss, Docket Item 61; on March 28, 2022, McKenzie responded, Docket Item 66; and on May 20, 2022, the defendants replied, Docket Item 67. While that motion was pending, however, the individual defendants—Johnson Lau, Jeffrey Yordon, Rudolf Kwan, and Timothy Cook—filed a suggestion of bankruptcy as to the corporate defendant, Athenex, Inc. ("Athenex"). Docket Item 69. After this Court stayed the matter, Docket Item 70, McKenzie moved to partially lift the stay so that the case could continue against the individual defendants, Docket Item 71. The individual defendants did not oppose the motion to partially lift the stay, Docket Item 72, so on September 6, 2023, this Court

lifted the stay as to the individual defendants and referred the case back to Judge Schroeder, Docket Item 73.

On September 29, 2023, Judge Schroeder issued a Report and Recommendation ("R&R") finding that the individual defendants' motion to dismiss should be granted and that the claims against Lau, Yordon, Kwan, and Cook should be dismissed. Docket Item 74. On October 13, 2023, McKenzie objected to the R&R, Docket Item 75; on November 3, 2023, the defendants responded to the objections, Docket Item 77; and on November 17, 2023, McKenzie replied, Docket Item 78.

A district court may accept, reject, or modify the findings or recommendations of a magistrate judge. 28 U.S.C. § 636(b)(1); Fed. R. Civ. P. 72(b)(3). The court must review *de novo* those portions of a magistrate judge's recommendation to which a party objects. 28 U.S.C. § 636(b)(1); Fed. R. Civ. P. 72(b)(3).

This Court has carefully and thoroughly reviewed the R&R; the record in this case; the objections, response, and reply; and the materials submitted to Judge Schroeder. Based on that *de novo* review, the Court accepts and adopts Judge Schroeder's recommendation to grant the defendants' motion and dismiss the claims against the individual defendants.

BACKGROUND[1]

Athenex is a "clinical stage biopharmaceutical company working to develop and commercialize new cancer treatments" that is headquartered in Buffalo, New York.

[1] In deciding a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), courts "accept all factual allegations as true and draw all reasonable inferences in favor of the plaintiff." *Trs. of Upstate N.Y. Eng'rs Pension Fund v. Ivy Asset Mgmt.*, 843 F.3d 561, 566 (2d Cir. 2016). The following facts are taken from the amended complaint,

Docket Item 56 at ¶ 22. The individual defendants—Lau, Yordon, Kwan, and Cook—were officers or executives of Athenex during the class period.[2] *Id.* at ¶¶ 23-26. More specifically, Lau was Chief Executive Officer and Chairman of the Board of Directors, *id.* at ¶ 23; Yordon was Chief Operating Officer and President of the Pharmaceutical Division, *id.* at ¶ 24; Kwan was Chief Medical Officer, *id.* at ¶ 25; and Cook was Senior Vice President of Global Oncology, *id.* at ¶ 26.

In 2011, Athenex licensed the drug Oraxol from Hanmi Pharm Co., Ltd. ("Hanmi"), a South Korean company. *Id.* at ¶ 29. Oraxol is a combination of paclitaxel, an intravenous cancer drug, and encequidar, an inhibitor developed by Hanmi that allows human cells to absorb orally administered paclitaxel. *Id.* at ¶¶ 28, 34, 36. After acquiring Oraxol in 2011, Athenex pursued FDA approval of the drug and conducted Phase 1 and Phase 2 studies in patients with metastatic breast cancer.[3] *Id.* at ¶ 29.

Docket Item 56, and any documents upon which it relies, *see Lentell v. Merrill Lynch & Co.*, 396 F.3d 161, 165 (2d Cir. 2005). The Court also considers the documents attached to the declaration of Douglas W. Green in support of the defendants' motion to dismiss, Docket Item 64, because they are either incorporated into the amended complaint by reference or matters of public record, *see Staehr v. Hartford Fin. Servs. Grp., Inc.*, 547 F.3d 406, 425 (2d Cir. 2008) ("[I]t is proper to take judicial notice of the *fact* that press coverage, prior lawsuits, or regulatory filings contained certain information, without regard to the truth of their contents . . . ." (emphasis in original)).

[2] The class period is August 7, 2019, to February 26, 2021. *See* Docket Item 56 at ¶ 163.

[3] "Phase 1 includes the initial introduction of an investigational new drug into humans. . . . These studies are designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness." 21 C.F.R. § 312.21(a)(1). "Phase 2 includes the controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug." 21 C.F.R. § 312.21(b).

In December 2015, Athenex began a Phase 3 clinical trial in ten Latin American countries.[4] *Id.* at ¶ 37. "The primary endpoint of the study was confirmed tumor response rate," also called the objective response rate here. *Id.* at ¶¶ 37, 58. "One common method of reviewing data and eliminating or reducing bias [in drug trials] is through the use of a Blinded Independent Central Review . . . , a third party that reviews clinical data and makes assessments." *Id.* at ¶ 58. Athenex hired Intrinsic Imaging LLC, a Massachusetts-based laboratory, to perform the blinded independent central review to assess the Phase 3 trial's objective response rate. *Id.*

In June 2017—while the Phase 3 trial was ongoing—Athenex issued 6.9 million shares of common stock at $11 per share through an initial public offering ("IPO"). *Id.* at ¶ 30. The IPO raised approximately $64 million "to fund operations, including the continued development of Oraxol." *Id.*

Shortly after the IPO, on October 5, 2017, Athenex issued a press release stating that an independent drug safety monitoring board had "unanimously recommended continuation" of the Phase 3 study, having been "reassured by the expected difference in safety profile between Oraxol and [intravenous] paclitaxel." *Id.* at ¶ 38 (internal quotation marks omitted). A few months later, on January 16, 2018, Athenex announced that the Food and Drug Administration ("FDA") had "provided positive feedback on the design of the currently ongoing" Phase 3 trial. *Id.* at ¶ 39. More specifically, Athenex reported that the FDA "indicated that if the study [met] the primary

[4] "Phase 3 studies are expanded controlled and uncontrolled trials. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling." 21 C.F.R. § 312.21(c).

endpoint with an acceptable Benefit/Risk profile, it could be adequate as a single comparative trial to support registration of Oraxol for a metastatic breast cancer indication in the United States." *Id.* (alteration in original) (internal quotation marks omitted). The January 16 press release also quoted Lau as stating that "the positive feedback from the FDA" on the Phase 3 trial "provides further validation of our regulatory pathway for Oraxol." *Id.* (internal quotation marks omitted). In other words, Athenex reported that the Phase 3 trial was going according to plan and that Oraxol was on track to receive FDA approval.

After those two positive press releases, Athenex issued another 4.765 million shares of common stock in a second public offering ("SPO") on January 25, 2018. *Id.* at ¶ 31. Athenex issued two more press releases on February 15 and September 5, 2018; the latter quoted Kwan as stating that "the unanimous recommendation by the [independent drug safety monitoring board] to continue this study represents the achievement of another critical milestone for Oraxol" and that Athenex "plan[ned] to provide these confidential unblinded data to regulatory authorities soon to discuss the marketing submission pathways." *Id.* at ¶ 40 (alteration in original) (internal quotation marks omitted).

Athenex concluded the Oraxol Phase 3 trial on July 25, 2019. *See id.* at ¶¶ 3, 37, 41. Almost two years later, on March 1, 2021, Athenex issued a press release titled "Athenex Receives FDA Complete Response Letter for Oral Paclitaxel Plus Encequidar for the Treatment of Metastatic Breast Cancer." *Id.* at ¶ 75 (internal quotation marks omitted). In that press release, Athenex announced that the FDA had denied the Oraxol new drug application and had issued a complete response letter, which "indicate[s] that

the review cycle for an application is complete and that the application is not ready for approval in its present form." *See id.* (internal quotation marks omitted).

According to Athenex's characterization of the complete response letter,[5] the FDA gave three reasons why the new drug application for Oraxol was not approved. *See id.* First, the FDA expressed concerns about the validity of the Phase 3 trial's objective response rate because "the [blinded independent central review] reconciliation and re-read process may have introduced unmeasured bias and influence on the [blinded independent central review]." *Id.* (internal quotation marks and emphasis omitted). Second, the FDA believed that Athenex needed to conduct a clinical trial in a patient population with metastatic breast cancer more representative of the patient population in the United States. *Id.* And third, the FDA was concerned about an increased safety risk for patients using Oraxol compared to those using intravenous paclitaxel. *Id.* at ¶ 76.

The market reacted quickly to the news that the FDA had not accepted Athenex's new drug application for Oraxol. On the date of the announcement, Athenex's stock price dropped from $12.10 per share to $5.46 per share. *Id.* at ¶ 80. The approximate 55% drop in share value wiped out $620 million of Athenex's market capitalization in a single day. *See id.* at ¶¶ 13, 80. This lawsuit was filed two days later, on March 3, 2021, alleging that Athenex and the individual defendants had "disseminated or approved [ ] false statements . . . , which they knew or deliberately disregarded were

[5] Pursuant to 21 C.F.R. § 20.61, the FDA has not publicly released the Oraxol complete response letter. *See* Docket Item 56 at ¶ 12 n.2.

misleading . . . and failed to disclose material facts necessary to make the statements . . . not misleading." *See* Docket Item 1 at ¶ 75.

LEGAL PRINCIPLES

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* (quoting *Twombly*, 550 U.S. at 556).

"Securities fraud claims are subject to heightened pleading requirements that the plaintiff must meet to survive a motion to dismiss." *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 99 (2d Cir. 2007). First, the complaint must satisfy the requirements of Federal Rule of Civil Procedure 9(b). *See ECA, Loc. 134 IBEW Joint Pension Tr. of Chi. v. JP Morgan Chase Co.*, 553 F.3d 187, 196 (2d Cir. 2009). Rule 9(b) provides that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b).

Second, the complaint must comply with the requirements of the Private Securities Litigation Reform Act ("PSLRA"), 15 U.S.C. § 78u-4(b). *See ECA*, 553 F.3d at 196. More specifically, "where a plaintiff's claims depend upon allegations that the defendant has made an untrue statement of material fact or that the defendant omitted a material fact necessary to make a statement not misleading, the plaintiff shall specify

each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading." *Gregory v. ProNAi Therapeutics Inc.*, 297 F. Supp. 3d 372, 394 (S.D.N.Y. 2018) (internal quotation marks and citation omitted).

DISCUSSION

I. ALLEGATIONS AND OBJECTIONS

McKenzie's amended complaint alleges that Athenex and the individual defendants made actionable statements trumpeting optimism about FDA approval when they "knew, or recklessly disregarded, but failed to disclose":

> (1) that Athenex's "decision to pursue FDA approval for Oraxol via the abbreviated [section] 505(b)(2) pathway[6] without the FDA's prior authorization created a significant risk that the [new drug application] would be rejected or that additional clinical studies would be required";
>
> (2) that "Oraxol's [new drug application] was at significant risk due to multiple undisclosed [chemistry, manufacturing, and controls] changes that had been made during the Phase 3 [t]rial that disrupted the 'comparability' between the prior data submitted in Oraxol's Phase 1 and 2 trials and the Phase 3 [t]rial";
>
> (3) that "the protocols for the evaluation of [t]rial data injected the potential for bias into the [blinded independent central review] process and risked undermining the certainty and reliability of the data Athenex presented; and"

[6] Section 505(b)(2) of the Food, Drug, and Cosmetic Act provides an abbreviated pathway for approval of "new drug products that include changes compared to an existing approved product, such as a new formulation, route of administration, or intended use." Docket Item 56 at ¶ 43. "A drug submitted via the [section] 505(b)(2) pathway can be approved based on prior data from studies not conducted by the applicant by relying on previous findings by the FDA of safety and effectiveness of an approved drug." *Id.* Here, "Athenex sought to rely on existing clinical data with respect to [intravenous] paclitaxel, which had already been approved by the FDA. However, Oraxol's other ingredient, encequidar, was not an FDA-approved substance." *Id.* at ¶ 44.

(4) that "there was a significant risk that the FDA would recommend that a new clinical trial of patients representative of the U.S. population be conducted."

See, e.g., Docket Item 56 at ¶ 101.

In the R&R, Judge Schroeder concluded that the individual defendants' statements were either nonactionable opinions or puffery.[7] *See* Docket Item 74 at 24-27. He also concluded that even if the statements could be characterized as false or misleading statements of fact, they still were not actionable because McKenzie had not plausibly alleged scienter. *See id.* at 20-24, 28-33. In support of those conclusions, Judge Schroeder determined that the factual assertions of three confidential witnesses were "fatally vague" and that McKenzie "stop[ped] short of alleging any *facts* that show that any individual defendant knew of the [four risks to FDA approval]." *Id.* at 21 (emphasis in original). As such, Judge Schroeder recommended that the defendants' motion to dismiss be granted as to the claims against the individual defendants. *Id.* at 34.

[7] "Certain types of statements, including puffery and opinion statements, are not actionable because they are not misleading." *Galestan v. OneMain Holdings, Inc.*, 348 F. Supp. 3d 282, 297 (S.D.N.Y. 2018). "Puffery is an optimistic statement that is so vague, broad, and non-specific that a reasonable investor would not rely on it, thereby rendering it immaterial as a matter of law." *In re Gen. Elec. Co. Sec. Litig.*, 857 F. Supp. 2d 367, 384 (S.D.N.Y. 2012); *see Rombach v. Chang*, 355 F.3d 164, 174 (2d Cir. 2004) ("People in charge of an enterprise are not required to take a gloomy, fearful[,] or defeatist view of the future; subject to what current data indicates, they can be expected to be confident about their stewardship and the prospects of the business that they manage." (internal quotation marks and citation omitted)). For a statement of opinion to be actionable, "a plaintiff must also show that (1) 'the speaker did not hold the belief [they] professed,' (2) 'the supporting fact[s] [they] supplied were untrue,' or (3) 'the speaker omit[ted] information . . . [that] makes the statement misleading to a reasonable investor.'" *Galestan*, 348 F. Supp. 3d at 298 (alterations in original) (quoting *Tongue v. Sanofi*, 816 F.3d 199, 209-10 (2d Cir. 2016)).

McKenzie raises three issues in his objections to Judge Schroeder's R&R. *See* Docket Item 75 at 11-30. First, he argues for the first time[8] that the individual defendants' statements about an agreement between Athenex and the FDA must have been false because, "[g]iven the FDA's rejection of the Oraxol [new drug application], either [Athenex] never had an agreement with the FDA . . . or [the individual defendants] self-evidently misrepresented its terms." *See id.* at 11-14. Second, he says that the individual defendants made actionable statements by "touting the Phase 3 [t]rial results" while omitting multiple serious risks to obtaining FDA approval. *See id.* at 14-26. And third, he argues that the factual assertions provided by his confidential witnesses adequately establish the individual defendants' scienter. *Id.* at 26-29.

II. ELEMENTS OF MCKENZIE'S CLAIMS

McKenzie brings claims under Exchange Act section 10(b), as implemented by 17 C.F.R. § 240.10b-5 ("Rule 10b-5"), and section 20(a). *See* Docket Item 56 at ¶¶ 172-86.

Section 10(b) makes it unlawful to "use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [Securities and

[8] "It is established law that a district judge will not consider new arguments raised in objections . . . that could have been raised before the magistrate but were not." *United States v. Hunt*, 440 F. Supp. 3d 221, 224 (W.D.N.Y. 2020) (internal quotation marks and citation omitted). But "[t]he Second Circuit has expressed skepticism regarding the proposition that district courts lack discretion to consider an issue first raised in a reply brief," and this logic has been applied to arguments raised for the first time in objections to an R&R. *See Levy v. Young Adult Inst., Inc.*, 103 F. Supp. 3d 426, 433 (S.D.N.Y. 2015) (citing *Booking v. Gen. Star Mgmt. Co.*, 254 F.3d 414, 418 (2d Cir. 2001)). This Court therefore will consider McKenzie's new argument, especially because the individual defendants addressed it in their response to his objections. *See* Docket Item 77 at 23-25.

Exchange] Commission may prescribe." 15 U.S.C. § 78j(b). The implementing regulation, Rule 10b-5, makes it unlawful "[t]o make any untrue statement of a material fact or to omit to state a material fact necessary . . . to make the statements made, in light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b-5. "To state a claim under [s]ection 10(b) and Rule 10b-5, a plaintiff must plead: (1) a misstatement or omission of material fact; (2) scienter; (3) a connection with the purchase or sale of securities; (4) reliance; (5) economic loss; and (6) loss causation." *Ark. Pub. Emps. Ret. Sys. v. Bristol-Meyers Squibb Co.* ("*APERS*"), 28 F.4th 343, 351-52 (2d Cir. 2022).

Section 20(a) "imposes joint and several liability on '[e]very person who, directly or indirectly, controls any person liable under any provision of [the Exchange Act] or of any rule or regulation [promulgated] thereunder.'" *In re Philip Morris Int'l Inc. Sec. Litig.*, 89 F.4th 408, 429 (2d Cir. 2023) (alterations in original) (quoting 15 U.S.C. § 78t(a)). To establish control person liability, "a plaintiff must show (1) a primary violation by the controlled person, (2) control of the primary violator by the defendant, and (3) that the defendant was, in some meaningful sense, a culpable participant in the controlled person's fraud." *ATSI*, 493 F.3d at 108. Being a "culpable participant" includes sharing the primary violator's scienter. *See In re Am. Int'l Grp., Inc., 2008 Sec. Litig.*, 741 F. Supp. 2d 511, 535-36 (S.D.N.Y. 2010). But "a party cannot be held liable for both a primary violation [under section 10(b) and Rule 10b-5] and as a control person [under section 20(a)]." *Id.* at 534.

To resolve McKenzie's objections to the R&R, the Court must determine whether he adequately alleges that the individual defendants made false or misleading

statements or omissions of material fact with the requisite scienter. *See* Docket Item 75 at 11-29; *see also In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 527 (S.D.N.Y. 2015) ("The Court highlights, and below addresses the allegations as to, these two elements [falsity and scienter] because consideration of them is sufficient to establish that neither [complaint] states a claim.").

A. Material Misstatements or Omissions

A fundamental element of securities fraud claims is "that the defendant made a statement that was 'misleading as to a material fact.'" *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 38 (2011) (emphasis omitted) (quoting *Basic Inc. v. Levinson*, 485 U.S. 224, 238 (1988)). "An alleged misrepresentation is material if there is a substantial likelihood that a reasonable person would consider it important in deciding whether to buy or sell shares of stock." *Singh v. Cigna Corp.*, 918 F.3d 57, 63 (2d Cir. 2019) (internal quotation marks and citation omitted).

"The veracity of a statement or omission is measured not by its literal truth, but by its ability to accurately inform rather than mislead prospective buyers." *APERS*, 28 F.4th at 354. An alleged material misstatement is actionable only if it "was false *at the time it was made*." *In re Lululemon Sec. Litig.*, 14 F. Supp. 3d 553, 571 (S.D.N.Y. 2014) (emphasis in original); *see Novak v. Kasaks*, 216 F.3d 300, 309 (2d Cir. 2000) (noting the Second Circuit's "refus[al] to allow plaintiffs to proceed with allegations of fraud by hindsight." (internal quotation marks and citation omitted)). "The Second Circuit has repeatedly stated that plaintiffs must do more than simply assert that a statement is false—'they must demonstrate with specificity why that is so,'" even at the motion to

dismiss stage. *See In re Lululemon*, 14 F. Supp. 3d at 571 (quoting *Rombach v. Chang*, 355 F.3d 164, 174 (2d Cir. 2004)).

As for omissions, "[s]ilence, absent a duty to disclose, is not misleading under [section 10(b) and] Rule 10b-5." *In re Synchrony Fin. Sec. Litig.*, 988 F.3d 157, 167 (2d Cir. 2021) (internal quotation marks and citation omitted). "[A] corporation is not required to disclose a fact merely because a reasonable investor would very much like to know the fact[; r]ather, an omission is actionable under the securities laws only when the corporation is subject to a duty to disclose the omitted facts." *In re Time Warner Inc. Sec. Litig.*, 9 F.3d 259, 267 (2d Cir. 1993). "This duty may arise when 'a corporate insider trad[es] on confidential information, a statute or regulation requir[es] disclosure,' or a statement is made that would be 'inaccurate, incomplete, or misleading' without further context." *In re Synchrony*, 988 F.3d at 167 (alterations in original) (quoting *Stratte-McClure v. Morgan Stanley*, 776 F.3d 94, 101 (2d Cir. 2015)). But "there is no duty to update vague statements of optimism or expressions of opinion." *In re Int'l Bus. Machs. Corp. Sec. Litig.*, 163 F.3d 102, 110 (2d Cir. 1998).

B. Scienter

Scienter is the "intent to deceive, manipulate, or defraud." *ECA*, 553 F.3d at 198 (internal quotation marks and citation omitted). "When deciding a motion pursuant to Rule 12(b)(6), a court must decide whether all facts taken together—that is, collectively—give rise to a strong inference that a maker of a statement acted with scienter." *In re Lululemon*, 14 F. Supp. 3d at 573 (citing *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 323 (2007)). Under the PSLRA, a complaint must "allege facts showing (1) that defendants had the motive and opportunity to commit fraud, or (2)

strong circumstantial evidence of conscious misbehavior or recklessness." *APERS*, 28 F.4th at 355 (internal quotation marks and citation omitted); *see* 15 U.S.C. § 78u-4(b)(2).

"The opportunity to commit fraud is generally assumed where the defendant is a corporation or a corporate officer." *In re MF Glob. Holdings Ltd. Sec. Litig.*, 982 F. Supp. 2d 277, 306 (S.D.N.Y. 2013). But "to raise a strong inference of scienter through motive and opportunity to defraud, [a plaintiff] must allege that [the defendants] benefitted in some concrete and personal way from the purported fraud." *ECA*, 553 F.3d 198 (internal quotation marks and citation omitted). "Allegations limited to the type of 'corporate profit' motive possessed by most corporate directors and officers do not suffice." *In re Lululemon*, 14 F. Supp. 3d at 573 (citing *Kalnit v. Eichler*, 264 F.3d 131, 142 (2d Cir. 2001)). "[T]he 'motive' showing is generally met when corporate insiders allegedly make a misrepresentation . . . to sell their own shares at a profit." *ECA*, 553 F.3d at 198.

"If no motive or opportunity (other than a generalized business motive) is shown, the circumstantial evidence of conscious misbehavior [or recklessness] must be correspondingly greater and show highly unreasonable behavior or that which evinces an extreme departure from the standards of ordinary care." *APERS*, 28 F.4th at 355 (internal quotation marks and citation omitted). "Circumstantial evidence can support an inference of scienter in a variety of ways, including where defendants (1) benefitted in a concrete and personal way from the purported fraud; (2) engaged in deliberately illegal behavior; (3) knew facts or had access to information suggesting that their public statements were not accurate; or (4) failed to check information they had a duty to

monitor." *Emps.' Ret. Sys. of Gov't of the Virgin Islands v. Blanford*, 794 F.3d 297, 306 (2d Cir. 2015) (internal quotation marks and citation omitted).

III. ANALYSIS

A. Section 10(b) and Rule 10b-5 Claims

McKenzie argues that the individual defendants made two types of material misstatements or omissions: (1) statements about an agreement between Athenex and the FDA regarding the primary endpoint of the Phase 3 trial, Docket Item 75 at 11-12; and (2) "statements touting the Phase 3 [t]rial results that were gravely misleading half-truths that omitted undisclosed risks" to FDA approval, *see id.* at 14-25. According to McKenzie, the individual defendants had knowledge of facts contradicting those statements at the time they were made. *See id.* at 26; *see also* Docket Item 56 at ¶ 177.

When "information contrary to the alleged misrepresentations is alleged to have been known by [the] defendants at the time the misrepresentations were made, the falsity and scienter [pleading] requirements are essentially combined." *In re JP Morgan Chase Sec. Litig.*, 363 F. Supp. 2d 595, 625 (S.D.N.Y. 2005); *see Rothman v. Gregor*, 220 F.3d 81, 89-90 (2d Cir. 2000). This Court therefore first addresses McKenzie's scienter allegations. And as noted above, that involves deciding whether McKenzie has "allege[d] facts showing (1) that [the] defendants had the motive and opportunity to commit fraud, or (2) strong circumstantial evidence of conscious misbehavior or recklessness." *See APERS*, 28 F.4th at 355 (internal quotation marks and citation omitted).

1. Motive and Opportunity

McKenzie argues that two facts establish the individual defendants' motive to make false or misleading statements. *See* Docket Item 56 at ¶¶ 81-90.

First, he points to a "September 2020 FDA Establishment Inspection Report . . . [stating that] both Lau and Kwan were deeply involved in [Athenex's] selection of one of the clinical research organizations that monitored the Phase 3 [t]rial and the 'country specific regulatory submissions' for each of the Latin American countries in which the [t]rial took place." *Id.* at ¶ 82. According to McKenzie, "[t]hat Lau and Kwan were involved in the selection of this [clinical research organization] comes as no surprise as each of the three [clinical research organizations] Athenex has utilized in its Oraxol clinical trials are related parties, a potential conflict of interest." *Id.* at ¶ 83.

The motive to "attract customers, finance current operations, and pursue strategic acquisitions ha[s] been routinely rejected by courts within the Second Circuit as insufficient to establish scienter." *Tamar v. Mind C.T.I., Ltd.*, 723 F. Supp. 2d 546, 555 (S.D.N.Y. 2010) (internal quotation marks and citation omitted) (also collecting cases). McKenzie does not provide any support for the proposition that a director's financial interest in a "related" company that does business with the corporate defendant is anything more than a general business motive. So the fact that the clinical research organizations were allegedly related to or subsidiaries of Athenex does not create an inference of motive on the part of the individual defendants.

Furthermore, the financial benefits offered to that clinical research organization—milestone payments—never materialized because they were dependent on the success of the Phase 3 trial. *See* Docket Item 56 at ¶¶ 83-84, 86. And Kwan is the only individual defendant alleged to have a personal financial interest in one of the clinical

research organizations. *See id.* at ¶ 84. So McKenzie has "not pointed to any specific benefit that would inure to [Kwan]"—or to any of the individual defendants—"that would not be either generalized to all corporate directors or beneficial to all shareholders."[9] *See Kalnit*, 264 F.3d at 142; *see also Chill v. Gen. Elec. Co.*, 101 F.3d 263, 267-268 (2d Cir. 1996).

Second, McKenzie notes that Athenex issued another 11.5 million public shares of stock in the SPO on September 10, 2020, and he argues that "[i]n issuing this [SPO] in the midst of the [c]lass [p]eriod before the truth had been revealed or the undisclosed risks that [the individual defendants] concealed had materialized, [Athenex] benefitted from an elevated share price." *See* Docket Item 56 at ¶¶ 87-90. But an individual defendant's alleged motive to artificially inflate a company's stock price in advance of a public offering is insufficient to raise an inference of scienter without some "instances of 'unusual' (that is, suspicious) stock sales." *In re Lottery.com, Inc. Sec. Litig.*, 2024 WL 454298, at *31 (S.D.N.Y. Feb. 6, 2024) (also collecting cases). And McKenzie does not contest the individual defendants' assertion that "[n]one of [them] sold stock at any point during the class period; indeed, three of them—Dr. Lau, Dr. Kwan, and Dr. Yordon—bought stock on the open market." Docket Item 77 at 27-28. So McKenzie has not raised an inference of scienter in connection with the second public offering.

For both of those reasons, McKenzie has not alleged facts creating an inference of scienter through motive and opportunity.

[9] If McKenzie means to allege that Kwan had a conflict in directing Athenex to do business with a related company in which Kwan had a financial interest, his argument fares no better. That might conceivably raise a claim against Kwan, but not one that would be relevant here because a potential breach of fiduciary duty would not create a motive to make false statements about the approval process for Oraxol.

2. Conscious Misbehavior or Recklessness

A plaintiff also may plead scienter through strong circumstantial evidence of conscious misbehavior or recklessness. *See APERS*, 28 F.4th at 355. And a plaintiff "may [ ] buttress an argument for strong circumstantial evidence with information obtained from confidential sources . . . [who are] 'described in the complaint with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged.'" *Glaser v. The9, Ltd.*, 772 F. Supp. 2d 573, 589 (S.D.N.Y. 2011) (quoting *Novak*, 216 F.3d at 314). Courts generally will credit confidential sources in two situations: (1) "when those sources' positions and/or job responsibilities are described sufficiently to indicate a high likelihood that they actually knew facts underlying their allegations"; or (2) "when independent [adequately pleaded] factual allegations corroborate a confidential source's statements." *Id.* at 590 (internal quotation marks and citation omitted).

"Two final requirements exist to credit confidential witness testimony." *Id.* "First, as is obvious, confidential sources cannot be used to merely parrot conclusory allegations contained in the complaint." *Id.* (alterations, internal quotation marks, and citation omitted). "Second, as with all allegations going to scienter, confidential source allegations must show that individual defendants actually possessed the knowledge highlighting the falsity of public statements; conclusory statements that defendants 'were aware' of certain information, and mere allegations that defendants 'would have' or 'should have' had such knowledge is insufficient." *Id.* at 590-91.

To create an inference of scienter through conscious misbehavior or recklessness, McKenzie relies on what three confidential witnesses ("CW1," "CW2," and "CW3") say. *See* Docket Item 56 at ¶¶ 43-61.

CW1 was a clinical research associate for Athenex who worked exclusively on the Phase 3 trial. *Id.* at ¶ 61. CW1 alleges that there were "many conversations pertaining to trial protocol discrepancies (*e.g.*, the size of tumors and whether a patient qualified to remain in the Phase 3 [t]rial) [that] occurred between doctors at the trial sites, who were unblinded to the data, and the [blinded independent central review] firm, which was supposed to be 'blinded.'" *Id.* According to CW1, these conversations "had the potential to introduce bias into the supposedly 'independent' review process and risked undermining the certainty and reliability of the [t]rial's ultimate data results." *Id.*

CW2 was a senior regulatory staffer at Athenex from mid-2018 until the fall of 2019. *Id.* at ¶ 41. CW2 alleges that Athenex's reliance on the section 505(b)(2) pathway was flawed "because [Athenex] failed to establish the required comparability between the prior paclitaxel clinical data and the data generated in Oraxol's Phase 3 [t]rial." *Id.* at ¶ 47. According to CW2, "by approximately mid-2019 the comparability issues between the prior-approved data and the Phase 3 [t]rial data were escalated to Athenex's Executive Committee," which included Kwan. *Id.* at ¶ 49. CW2 eventually helped to create a "series of PowerPoint presentations outlining the serious risks to obtaining regulatory approval due to these comparability issues." *Id.* CW2 says that Lau "was aware of these issues and their potential to derail FDA approval through his communications with [ ] Kwan and [E. Douglas] Kramer," Athenex's Senior Vice President for Regulatory Affairs. *Id.* And CW2 says "that the comparability issues between the prior-approved data and the Phase 3 [t]rial data were also raised at a Global Team meeting attended by executives from all three of [Athenex's] segments

and members of the Executive Committee that occurred in Buffalo, New York[,] in October 2019." *Id.* at ¶ 50.

CW2 further asserts that "there were major changes to [the chemistry, manufacturing, and controls practices] implemented by Athenex in its Phase 3 [t]rial that raised numerous 'comparability issues,'" *id.* at ¶ 53, and that these "comparability issues were raised [both] in the Project[10] and Global Team [m]eetings" and in the series of PowerPoint presentations that CW2 helped prepare, *see id.* As for the issues concerning study population, CW2 alleges that "the risk that the FDA would recommend that Athenex conduct a new clinical trial of patients representative of the population of the U.S. was something that had been widely discussed at Athenex, including at Project Team [m]eetings, and [ ] Kwan and Lau were aware of this issue as well." *Id.* at ¶ 56.

CW3 reviewed "proposed [chemistry, manufacturing, and controls] literature that was to be included in Athenex's submissions to the FDA seeking approval for Oraxol." *Id.* at ¶ 54. CW3 believed that "extensive" bridging studies were necessary following the major changes to Athenex's practices, and "[i]n CW3's professional opinion, Athenex's failure to provide sufficient information to the FDA in this regard created a substantially high likelihood that the [new drug application] for Oraxol would be rejected or that additional studies would be required by the FDA." *Id.*

[10] The monthly "Project Team" meetings included CW2, Kramer, Vice President of Preclinical Operations Michael Smolinski, two outside regulatory consultants, Senior Director of Quality Inspections Michael Scribner, Senior Director of Clinical Operations Jane Devane, Director of Clinical Operations John Goldfinch, "and others." Docket Item 56 at ¶ 48. CW2 does not say who regularly attended the "Global Team" meetings, *see id.* at ¶¶ 50, 53, but CW2 alleges that the "Executive Committee" was "comprised of [Athenex's] U.S.-based senior leadership including [ ] Kwan," *id.* at ¶ 49.

The confidential witnesses' factual assertions are insufficient to create an inference of conscious misbehavior or recklessness by any of the individual defendants. First, none of the confidential witnesses say anything about Athenex's interactions with the FDA, so none of them shed any light on any alleged "agreement." Moreover, the allegations made by CW1 and CW3 include only their own professional opinions and, in the case of CW1, conversations between the blinded independent central review firm's employees and doctors at the trial sites—not communications that address what the individual defendants knew.

CW2 attempts to make a tenuous connection among PowerPoint presentations, Project Team meetings, Global Team meetings, Kwan's role on Athenex's Executive Committee, and a meeting in October 2019. But even if CW2 "attended and made presentations at multiple meetings with Athenex's senior leadership, including [ ] Kwan, during which the likelihood that Oraxol's [new drug application] would not be approved . . . was presented and discussed," *see* Docket Item 56 at ¶ 8, that still does not raise an inference of conscious misbehavior or recklessness. Contrary to McKenzie's argument, Kwan and the other individual defendants were not obligated to disclose the substantial risks to FDA approval "simply because [those risks] may [have] be[en] relevant or of interest to a reasonable investor." *See Resnik v. Swartz*, 303 F.3d 147, 154 (2d Cir. 2002); *see also In re Sanofi*, 87 F. Supp. 3d at 534 ("The AG Funds plaintiffs emphasize that defendants knew about the design shortcomings in the Lemtrada clinical trials . . . yet failed to disclose that interim feedback . . . ma[king] their optimistic projections about FDA approval false and misleading. But the inference of scienter does not follow from the fact of non-disclosure." (internal citations omitted)).

And CW2's unsubstantiated assertion that Lau and Kwan were "aware" of some of the risks certainly falls short of creating an inference of conscious misbehavior or recklessness.[11]

Even more fundamentally, "[alt]hough the [confidential witnesses] offer their thoughts and opinions as to various [issues related to FDA approval], they do not establish what contradictory information the [individual defendants] had and the connection (temporal or otherwise) between that information and the statements at issue." *See In re Lululemon*, 14 F. Supp. 3d at 581-82 (also collecting cases). For instance, the confidential witnesses do not provide facts suggesting that, during the earnings call on August 7, 2019, Kwan knew that his statement about the blinded independent central review firm being "completely blinded to treatment assignment" was false. *See* Docket Item 56 at ¶ 37 (emphasis omitted); *see also* Docket Item 64-7 at 12. The same is true concerning the individual defendants' statements about: (1) Athenex's

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[11] McKenzie may be relying on what is known as the "core operations doctrine," which "permits an inference that a company and its senior executives have knowledge of information concerning the 'core operations' of a business." *Das v. Rio Tinto PLC*, 332 F. Supp. 3d 786, 816 (S.D.N.Y. 2018) (internal quotation marks and citation omitted).

> Whether a plaintiff may rely on the core operations doctrine in light of the PSLRA has not been decided by the Court of Appeals for the Second Circuit. However, the Second Circuit has commented that the doctrine can provide supplemental support for allegations of scienter, even if it cannot establish scienter independently. While courts in the Second Circuit have questioned the continuing viability of the doctrine, the majority consider the core operations allegations to constitute supplementary, but not an independent, means to plead scienter.

*Schwab v. E*TRADE Fin. Corp.*, 258 F. Supp. 3d 418, 434 (S.D.N.Y. 2017) (alterations, internal quotation marks, and internal citations omitted). Because McKenzie fails to establish the individual defendants' scienter on any other basis, the core operations doctrine does not help him here.

purported agreement with the FDA regarding the primary endpoint of the Phase 3 trial,[12] *see* Docket Item 56 at ¶¶ 67-68, 102; (2) Athenex's chemistry, manufacturing, and controls practices, *id.* at ¶¶ 100, 104, 111, 122-23; and (3) Athenex's decision to follow

[12] McKenzie's argument regarding Athenex's purported agreement with the FDA, *see* Docket Item 75 at 11-14, has some intuitive appeal. But it fails because the individual defendants never said that the FDA had promised to approve the Oraxol new drug application so long as the Phase 3 trial achieved a positive overall response rate. *Compare* Docket Item 56 at ¶ 39 (press release from January 16, 2018, stating that "if the study [met] the primary endpoint with an acceptable Benefit/Risk profile, it *could be adequate* as a single comparative trial to support registration of Oraxol for a metastatic breast cancer indication in the United States." (alteration in original) (emphasis added) (internal quotation marks omitted)), *with id.* at ¶ 68 (statement by Kwan on August 7, 2019, that "the FDA [had] previously provided positive feedback to Athenex that [it] would accept the results of this one pivotal trial for license application in the U.S. if the primary endpoint is met." (emphasis and internal quotation marks omitted)). When those statements are considered in context, *see Rombach*, 355 F.3d at 173, the individual defendants clearly were speaking about the FDA's decision to require only the Phase 3 trial's objective response rate, as opposed to also requiring the trial's progression-free survival and overall survival rates, *see, e.g.*, Docket Item 56 at ¶ 68 (statement by Lau on August 7, 2019, that the FDA "do[es] not even need the [progression-free survival] and [overall survival data]. Those are additional. What [the FDA] request[ed] is the ORR, overall response rate, as defined in the protocol to reach statistical significance . . . ."). What is more, even if the individual defendants made statements promising that the FDA's approval of the Oraxol new drug application would be based solely on the Phase 3 trial's objective response rate, the amended complaint makes clear that Athenex's investors nevertheless understood that other factors still were integral to regulatory approval. *See id.* at ¶¶ 70-71 (discussing the individual defendants' responses to investor questions about Athenex's chemistry, manufacturing, and controls practices and the Phase 3 trial's safety data). Therefore, the statements about Athenex's agreement with the FDA are insufficient as a matter of law to state a claim. *See, e.g.*, *Skiadas v. Acer Therapeutics Inc.*, 2020 WL 3268495, at *9 (S.D.N.Y. June 16, 2020) ("No reasonable investor could interpret the statement that the FDA 'provided . . . guidance on the expected presentation of existing clinical data' to mean that the FDA had indicated that the [clinical trial] data were adequate to assure FDA approval."); *see also Halperin v. eBanker USA.com, Inc.*, 295 F.3d 352, 359 (2d Cir. 2002) ("In all cases, however, the court must keep in mind that a complaint fails to state a claim of securities fraud if *no reasonable investor* could have been misled about the nature of the risk when he invested." (emphasis in original)).

the section 505(b)(2) pathway or the representativeness of the Phase 3 trial's study population,[13] *see generally id.* at ¶¶ 91-157.

In sum, McKenzie has failed to allege any facts that could plausibly give rise to an inference of scienter on the part of any of the individual defendants. There is nothing to suggest that the individual defendants' financial interests gave them some reason to knowingly make false statements, and the fact that Athenex participated in another public offering during the class period is not evidence of fraudulent motive on the part of any individual defendant. Furthermore, the factual allegations made by the three confidential witnesses fail to establish circumstantial evidence of conscious misbehavior or recklessness by any individual defendant. For all those reasons, any allegedly false or misleading statement made by an individual defendant is inactionable due to a lack of scienter. *See, e.g.*, *Novak*, 216 F.3d at 309 ("Corporate officials need not be clairvoyant; they are only responsible for revealing those material facts reasonably available to them."); *cf. City of Westland Police & Fire Ret. Sys. v. MetLife, Inc.*, 129 F. Supp. 3d 48, 69 (S.D.N.Y. 2015) ("To allege adequately that a statement of fact (*e.g.*, 'the New York Yankees today have the best record in baseball') is false within the

[13] Based on its thorough review of the amended complaint, the Court cannot find any statements by the individual defendants addressing Athenex's decision to follow the section 505(b)(2) pathway or the representativeness of the Phase 3 trial's population. In fact, McKenzie's amended complaint comes dangerously close to "puzzle pleading"—a form of pleading that is insufficient to state a claim under the PSLRA. *See Constr. Laborers Pension Trust for S. Cal. v. CBS Corp.*, 433 F. Supp. 3d 515, 530 (S.D.N.Y. 2020) (defining puzzle pleading as a complaint "marked by lengthy block quotes followed by pro forma reasons why the statements quoted are allegedly false"); *see also Born v. Quad/Graphics, Inc.*, 521 F. Supp. 3d 469, 478-79 (S.D.N.Y. 2021) (dismissing complaint for puzzle pleading where plaintiffs "excerpt[ed] statements from nearly every public disclosure document and related investor call [ ] conducted during the [c]lass [p]eriod, relying primarily on bolded text in half-page block quotations to identify the allegedly misleading statements.").

securities laws, a plaintiff need only plead facts that, if true, would be sufficient to show . . . that the statement is, in fact, false—*i.e.*, that the Yankees today do not have the best record in baseball.").

C. Section 20(a) Claims

Judge Schroeder also recommended that the section 20(a) claims against the individual defendants be dismissed. *See* Docket Item 74 at 33. McKenzie does not object to that recommendation, and neither 28 U.S.C. § 636 nor Federal Rule of Civil Procedure 72 requires a district court to review the recommendation of a magistrate judge to which no objections are raised. *See Thomas v. Arn*, 474 U.S. 140, 149-50 (1985).

Nevertheless, the Court has reviewed that portion of the R&R and agrees with it. More specifically, because McKenzie's scienter allegations are insufficient under section 10(b) and Rule 10b-5, they also are insufficient under section 20(a). *See In re Am. Int'l Grp.,* 741 F. Supp. 2d at 535 ("With respect to the third element of control person liability under [s]ection 20(a), the pleading requirements for 'culpable participation' are satisfied by the same allegations that satisfy the scienter pleading requirements."). The Court therefore accepts Judge Schroeder's recommendation to dismiss the section 20(a) claims against the individual defendants.

D. Request for Leave to Amend

In his response to the defendants' motion to dismiss, McKenzie asked for leave to amend his amended complaint "[s]hould the Court grant [the defendants'] motion to dismiss." Docket Item 66 at 32. Judge Schroeder recommended that this request be

denied. *See* Docket Item 74 at 34. This Court agrees and denies McKenzie's request for leave to amend.

Under Federal Rule of Civil Procedure 15(a)(2), "[a] court should freely give leave [to amend] when justice so requires." Fed. R. Civ. P. 15(a)(2). This "permissive standard . . . is consistent with [the Second Circuit's] strong preference for resolving disputes on the merits." *Loreley Financing (Jersey) No. 3 Ltd. v. Wells Fargo Sec., LLC*, 797 F.3d 160, 190 (2d Cir. 2015) (internal quotation marks and citation omitted). "But a court need not always allow a party to replead simply because it asked. In particular, denial of leave to amend is proper where the request gives no clue as to how the complaint's defects would be cured." *Noto v. 22nd Century Grp., Inc.*, 35 F.4th 95, 107 (2d Cir. 2022) (internal quotation marks and citation omitted).

McKenzie responded to the defendants' motion to dismiss on March 28, 2022. *See* Docket Item 66. He has had more than two years to address the deficiencies raised in the defendants' motion and to comply with this District's Local Rules, which require "[a] movant seeking to amend or supplement a pleading [to] attach an unsigned copy of the proposed amended pleading as an exhibit to the motion." Loc. R. Civ. P. 15(a). He has not done so, and he therefore provides no reason to believe that another amended complaint might do the trick.[14] McKenzie's request for leave to amend therefore is denied. *See, e.g.*, *Attestor Value Master Fund v. Rep. of Argentina*, 940 F.3d 825, 833 (2d Cir. 2019) (acknowledging that leave to amend may be futile where plaintiff "fails to specify either to the district court or to the court of appeals how

[14] Additionally, some courts have held that "amendment should be granted less freely when a complaint subject to the PSLRA is dismissed." *See In re Longtop Fin. Techs. Ltd. Sec. Litig.*, 939 F. Supp. 2d 360, 391-92 (S.D.N.Y. 2013).

amendment would cure the pleading deficiencies in its complaint." (internal quotation marks and citation omitted)).

CONCLUSION

For the reasons stated above and in the R&R, the defendants' motion to dismiss, Docket Item 61, is GRANTED as to the individual defendants. The Clerk of the Court shall dismiss Lau, Yordon, Kwan, and Cook as defendants in this matter. The stay of the case against Athenex, Docket Item 70, shall remain in place, and the Court reserves decision on the portions of the defendants' motion to dismiss the claims against Athenex until that stay is lifted. The case is referred back to Judge Schroeder for further proceedings consistent with the referral order of April 28, 2021, Docket Item 14.

SO ORDERED.

Dated: May 28, 2024
Buffalo, New York

/s/ Lawrence J. Vilardo
LAWRENCE J. VILARDO
UNITED STATES DISTRICT JUDGE